



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,694	04/03/2002	Akihiko Sano	0020-4976 P	5505
2292	7590	06/16/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/089,694	<b>Applicant(s)</b> SANO ET AL.	
	<b>Examiner</b> Susan T. Tran	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/14/04</u> . | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Receipt is acknowledged of applicant's Information Disclosure Statement filed 04/03/02 and 08/09/02, Preliminary Amendment to the Specification filed 04/03/02, and Status Inquiry Letter filed 12/05/03.

### ***Specification***

The abstract of the disclosure is objected to because this application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b) on a separate sheet. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. US 5,324,519.

Dunn teaches a composition comprising biodegradable polymer capable of forming a biodegradable microporous, solid or gelatinous polymer matrix useful as an implant in animals (see abstract). The composition comprises an active agent, a thermoplastic polymer, a pore forming agent, and a curing agent (column 2, lines 11 through column 3, lines 1-10). The active agent can be selected from vaccines (column 12, lines 33-35).

Dunn is silent as to the teaching of particle containing carbonate, however, it is the position of the examiner that the polymer matrix of Dunn contains carbonate because Dunn teaches that the prepolymer ingredients may release a pore-forming moiety such as, carbon dioxide and the like (column 2, lines 66-68). Accordingly, such language indicates that the organic solvent or the pore forming agent, which is the claimed substance that reacted with the carbonate to generate carbon dioxide. Thus, it would have been obvious for one of ordinary skill in the art to modify the biodegradable polymer composition of Dunn to include the carbon in the matrix with the expectation to provide a polymer composition that can be administered to an implant site by injection without the need for surgical incision.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujioka et al. and Dunn et al. US 5,324,519.

Fujioka teaches a sustained release composition comprising active core and silicone elastomer as a carrier (column 2, lines 17-27). The composition further comprises stabilizer, preservative, soothing agent, solubilizer, plasticizer, and release

Art Unit: 1615

controlling agent (column 4, lines 40-60). The composition is suitable for implantation into body cavity of the like (column 5, lines 6-12).

Fujioka is silent as to the teaching of vaccine as the active agent.

Dunn teaches an implantable composition comprising biodegradable polymer capable of forming a biodegradable microporous, solid or gelatinous polymer matrix useful as an implant in animals (see abstract). The composition comprises vaccine as an active agent (column 12, lines 33-35). Thus, it would have been obvious for one of ordinary skill in the art to modify the sustained release composition of Fujioka using vaccine as the bioactive agent in view of the teaching of Dunn with the expectation to provide a sustained release implantable composition that can be administered to an implant site by injection without the need for surgical incision.

### ***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Reul et al., Schmitt, Coutel et al., and Starling et al. are cited as of interest for the teaching of implantable composition.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE  
SUPERVISORY/PATENT EXAMINER  
TECHNOLOGY CENTER 1600